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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,573	10/24/2003	Sheng Li	NDTCO.020A	9055

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EXAMINER

BURKHART, MICHAEL D

ART UNIT PAPER NUMBER

1633

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/692,573

Applicant(s)

LI ET AL.

Examiner

Michael D. Burkhart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. ____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/28; 12/23; 1/30</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Priority

This application was filed 10/24/2003 and makes no claims to prior applications, thus the invention is granted a priority date of 10/24/2003.

Information Disclosure Statement

The information disclosure statement filed 2/28/2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the FR 2 805 270 application referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites a polymer having a "weight average molecular weight" in a certain range. The meaning of this term is unclear, as it cannot be determined if the specified weight range is

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the actual weight or an average weight. Therefore the metes and bounds of the claimed subject matter are unclear.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 12-20 of U.S. Patent No. 6,878,374 in view of U.S. Patent No. 6,379,966. Claim 1 of the '374 patent recites a polymer of recurring units represented by formula (I). Formula I comprises acetal groups, and may comprise additional acetal and amide groups at the Y position. The X position may be an ester (i.e. C(O)OR¹), an amide, or "VZ", wherein V is a labile linker group and Z is one of the polycations listed in claim 1 (e.g. poly(ethyleneimine), polylysine, etc.). Absent evidence to the contrary, poly(ethyleneimine) comprises a tertiary amine group. Claims 3 and 5 of the '374 patent recite polymers in which the polycation is between 200-100,000 daltons. The specification reveals similar polymers to be "gels" or "hydrogels" (column 1, lines 64 - 66), hence the claimed

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polymer is considered to be water-swellaable, absent evidence to the contrary. Claim 14 of '374 recites the polymer with a VZ group complexed with a nucleic acid. If one looks to the specification for guidance on the broad genus of nucleic acids, it is noted DNA and RNA are revealed (column 6, lines 46 - 49). Claim 18 of '374 recites a method of transfecting a cell comprising contacting the cell with the polymer complexed with the nucleic acid. If one looks to the specification for guidance on the broadly claimed genus of cells, it is noted that the Examples teach transfection of the human 293 cell line with low levels of cytotoxicity (Examples 26-28).

The '374 patent does not specifically teach the use of double stranded RNA.

The '966 patent teaches polymers and methods for transfection of nucleic acids into cells (see abstract), and that the term nucleic acids includes, inter alia, ribozymes and double stranded RNA (column 6, lines 14 - 39).

The instantly claimed polymers and methods are essentially taught by the '374 patent except for the use of double-stranded RNA. It would have been obvious to one of skill in the art, seeking to transfect a cell with double stranded RNA (i.e. ribozymes) to modify the teachings of the '374 patent to include double stranded RNA, as taught in the '966 patent. This is because both patents teach the use of similar polymers to be useful and non-toxic ways to transfect cells with nucleic acids, and that the choice of nucleic acid is merely a matter of design, e.g. it is dependent on what the goals of the skilled artisan might be. Given the teachings of the cited references and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be considered, absent evidence to the contrary, that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

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Claims 1-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-42 of U.S. Patent Publication 2005/0049387 A1 (a notice of allowance was issued for the corresponding application, 10/651,394, on 12/13/2004 and the issue fee paid on 2/28/2005, hereinafter the '394 application) in view of U.S. Patent No. 6,379,966. Claim 1 of the '394 application recites a polymer of recurring units represented by formulas (I) or (II). Formulas I and II comprise acetal groups at the "A" position. The "Z" position may be an ester (i.e. $C(O)OR^1$), an amide, or "VU", wherein V is a labile linker group and U is one of the polycations listed in claim 1 (e.g. poly(ethyleneimine), polylysine, etc.). Position D may be a carboxylic ester, carboxylic amide, urea, or urethane. Absent evidence to the contrary, poly(ethyleneimine) at the least comprises a tertiary amine group. Claims 3, 5 and 9 of the '394 application recite polymers in which the polycation is between 200-100,000 daltons. The specification reveals similar polymers to be "gels" or "hydrogels" (§ [0006], last four lines), hence the claimed polymer(s) are considered to be water-swellaable, absent evidence to the contrary. Claims 14 and 34 of '394 recite the polymer with a VU group complexed with a nucleic acid, which may be DNA or RNA. Claims 18 and 38 of '394 recite a method of transfecting a cell comprising contacting the cell with the polymer complexed with the nucleic acid. If one looks to the specification for guidance on the broadly claimed genus of cells, it is noted that the Examples teach transfection of the human 293 cell line with low levels of cytotoxicity (Examples 52-56).

The '394 application does not specifically teach the use of double stranded RNA.

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The '966 patent teaches polymers and methods for transfection of nucleic acids into cells (see abstract), and that the term nucleic acids includes, inter alia, ribozymes and double stranded RNA (column 6, lines 14 - 39).

The instantly claimed polymers and methods are essentially taught by the '394 application except for the use of double-stranded RNA. It would have been obvious to one of skill in the art, seeking to transfect a cell with double stranded RNA (i.e. ribozymes) to modify the teachings of the '394 application to include double stranded RNA, as taught in the '966 patent. This is because both patents teach the use of similar polymers to be useful and non-toxic ways to transfect cells with nucleic acids, and that the choice of nucleic acid is merely a matter of design, e.g. it is dependent on what the goals of the skilled artisan might be. Given the teachings of the cited references and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be considered, absent evidence to the contrary, that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhart
Examiner
Art Unit 1633



DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER